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June 5, 2025

VIA ECF

Hon. Evelyn Padin, U.S.D.J. United States District Court for the District of New Jersey 50 Walnut Street Newark, NJ 07102

Re: Novartis AG, et al., v. Novadoz Pharmaceuticals, et al., Civil Action No. : 25-849

Dear Judge Padin:

This office, along with Debevoise & Plimpton LLP, represents plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation (together, "Novartis" or "Plaintiffs") in the above referenced matter against Defendants Novadoz Pharmaceuticals LLC, MSN Pharmaceuticals Inc., and MSN Laboratories Private Limited (together, "MSN" or "Defendants"). We write on behalf of Novartis, in response to the Third Circuit's June 4, 2025 Order (ECF No. 53) granting MSN's motion for a limited remand in the appeal of this Court's March 17, 2025 Opinion (ECF No. 32; the "PI Opinion").

We call to the Court's attention the timing of the limited remand given MSN's expressed intention to disrupt the status quo. There is currently a patent judgment in place blocking MSN from launching its generic valsartan/sacubitril products at least until July 16, 2025. However, MSN has indicated it wants to launch as soon as possible, absent court orders preventing it from doing so. See ECF Nos. 49, 50. Thus, as of July 16, MSN would be in position to launch its look-alike generic valsartan/sacubitril tablets—which, to date, have not been available in the market. Such an outcome would irreparably harm Novartis by stripping it of control over the reputation and goodwill associated with the ENTRESTO® trade dress—a harm that cannot be unwound or easily recompensed.

In light of the foregoing and to provide the parties and the Third Circuit the time needed to address these issues before the July 16 date lapses, Novartis respectfully requests that the Court address this matter as soon as practicable, based on the extensive briefing the parties already have provided (see e.g., ECF Nos. 45, 46) and the extensive work this Court has done in issuing two, lengthy opinions (see ECF Nos. 32, 51). Novartis further requests, however the Court rules on the limited remand, that it also treat this letter as a motion for an injunction pending appeal pursuant to Federal Rule of Civil Procedure 62(d) and grant a limited injunction to preserve the status quo pending appeal, for all of the reasons set forth in Novartis's motion for preliminary injunction (ECF Nos. 4-1–4-110, 17–17-6), opposition to MSN's motion to stay (ECF No. 42), and briefing on reconsideration (ECF No. 43).

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We appreciate the Court's attention to the time-sensitive nature of this matter.

/s/ *Mark M. Makhail* Mark M. Makhail

cc: All Counsel of Record (via ECF)